UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	Case No. 14-cv-5151
ABBVIE, INC., et al.,	:	
Defendants.	:	

[PROPOSED] ORDER

The matter is before the Court on Defendants' Motion to Dismiss the Complaint. Upon consideration of the contentions and arguments of the Parties, the Court hereby **ORDERS**:

Defendants' Motion to Dismiss is **GRANTED**.

Count II of the Complaint is dismissed with prejudice.

Count I of the Complaint is dismissed with prejudice to the extent it is premised on the AndroGel settlement agreement.

Dated: _____

_____
The Honorable Harvey Bartle, III
United States District Judge

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FEDERAL TRADE COMMISSION,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	Case No. 14-cv-5151
ABBVIE, INC., et al.,	:	ORAL ARGUMENT REQUESTED
Defendants.	:	

DEFENDANTS' MOTION TO DISMISS COMPLAINT

Defendants AbbVie, Inc., Abbott Laboratories, Unimed Pharmaceuticals, LLC, Besins Healthcare, Inc., and Teva Pharmaceuticals USA, Inc. hereby move this Court pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for an order dismissing with prejudice Count II of the Complaint and Count I to the extent it is premised on the settlement agreement that resolved patent litigation between various Defendants concerning the drug AndroGel (as described in the accompanying Memorandum in Support). Pursuant to Local Rule 7.1, this motion is based upon the Memorandum in Support of Defendants' Motion to Dismiss, and accompanying sealed exhibits, dated November 12, 2014. Defendants request that the Court hear oral argument on the motion at a date and time to be determined by the Court.

Dated: November 12, 2014

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS COMPLAINT

(PUBLIC VERSION—CONFIDENTIAL INFORMATION REDACTED)

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INTRODUCTION

The complaint filed by the Federal Trade Commission ("FTC") is a prime example of a plaintiff asserting a legal claim without the necessary facts to support such a claim. The FTC claims that a 2011 settlement agreement between Defendants Abbott Products, Inc., Unimed Pharmaceuticals, Inc., and Besins Healthcare, Inc., on the one hand,[1] and Teva Pharmaceuticals USA, Inc., on the other, to resolve patent litigation concerning the drug AndroGel is a so-called "reverse payment" settlement that violates the FTC Act under *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). But the facts as alleged by the FTC differ from *Actavis* in nearly every key respect, and the concerns that led the Supreme Court to hold that a narrow subset of settlements may sometimes raise antitrust concerns are not present here. This motion challenges Count II of the FTC's complaint, as well as Count I (a claim for monopolization) to the extent it is based on the 2011 AndroGel settlement. The FTC's complaint fails as a matter of law and should be dismissed.

First, the AndroGel settlement does not contain any payment at all, much less a "reverse payment" as that term is described in *Actavis*. This is not a situation, as alleged in *Actavis*, where the brand manufacturer/patent holder is alleged to have paid many millions of dollars to the generic manufacturer/patent challenger in exchange for business deals claimed to be a sham. The only consideration in the parties' AndroGel settlement is an early-entry license that permits Teva to sell its AndroGel product beginning later this year, nearly *six years* before the patent covering AndroGel expires. The settlement thus reflects a classic compromise on the date of early entry, which the

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[1] The complaint often glosses over the fact that the various agreements discussed herein were entered into by different corporate entities. This motion notes the precise corporate entity that entered into each transaction but otherwise uses "AbbVie" as a term of convenience to refer to AbbVie Products LLC and companies to which it shares some relation, including AbbVie, Inc., Abbott Laboratories, Abbott Products, Inc., Solvay Pharmaceuticals, Inc., and Unimed Pharmaceuticals, LLC. Defendants reserve all rights relating to the fact that the entities within these definitions are distinct. In addition, Defendant Besins Healthcare Inc. joins in this motion to the extent the claims against Besins are premised on an alleged "reverse payment" under *Actavis*.

Supreme Court in *Actavis* held was lawful, and the FTC itself has long maintained creates no antitrust concerns.

To try to support its claim of a "payment," the FTC points to one of two separate agreements between Teva and a different AbbVie-related entity. That was an agreement with Abbott Laboratories, pursuant to which AbbVie gave Teva the option to purchase supply of a different product—TriCor—to then re-sell under Teva's label. This supply option agreement is not a "reverse payment" under *Actavis*. To begin with, the agreement contains no payments from *any* AbbVie entity to Teva. On the contrary, *Teva* agreed to pay money *to* AbbVie, in the form of production costs and royalties. The only money Teva received came not from AbbVie, but from consumers who purchased a lower-cost alternative product. There is nothing "reverse" about this transaction. Moreover, the option supply agreement affirmatively *created* competition: as the FTC concedes, it gave consumers access to lower-priced generic versions of TriCor earlier than otherwise would have occurred. An agreement that permits a generic manufacturer to earn money by selling a lower-priced alternative to consumers is not actionable under *Actavis*.

Faced with this reality, the FTC distorts the supply option agreement based on an allegation the FTC does not (and cannot) make. The FTC argues that the TriCor supply option agreement is a reverse payment. This argument is based on the FTC's view that it otherwise made no business sense for AbbVie to supply Teva with TriCor because Teva had no other means of introducing a competing TriCor product. Over and above the fact that an agreement *creating* competition cannot give rise to an antitrust claim, the FTC's theory is based on the premise that AbbVie *knew* about the FDA obstacles to Teva marketing TriCor any other way. Critically, however, the FTC *does not allege this*. This omission was deliberate—the FTC knows, based on its investigation, that AbbVie did not know that Teva could not otherwise come to market. Absent this allegation, the FTC's entire

case collapses, as the FTC's complaint contains no other allegations supporting its theory that the TriCor supply option agreement was payment for the AndroGel settlement.

Equally important, the FTC does not plausibly allege that the TriCor supply option agreement led to any "delay" on the license for Teva's AndroGel product, which is the crux of a claim under *Actavis*. The complaint itself belies any such assertion by alleging that another company (Perrigo) settled similar litigation involving the same drug and same patent at nearly the same time for [redacted]—even though the FTC concedes the Perrigo deal contained no additional payment whatsoever and there was no contemporaneous other business agreement with Perrigo. When Challenger A (here, Teva) and Challenger B (here, Perrigo) settle patent litigation over the same drug [redacted], even though Challenger A allegedly received a reverse payment and Challenger B indisputably did not, there is no plausible basis for alleging that the supposed reverse payment caused any "delay" in Challenger A's entry—otherwise, Challenger B (which received no payment) would not have plausibly accepted [redacted] without a payment. Yet that is exactly what happened here. The Perrigo settlement confirms that the FTC's allegations about supposed "delay" caused by the TriCor supply option agreement are utterly implausible.

Second, even assuming *arguendo* that the TriCor supply option agreement was a "reverse payment" (and it was not), the FTC's complaint fails for the independent reason that it does not properly allege that the supposed payment was "large" and "unexplained." Such allegations are required to state an *Actavis* claim, as multiple courts have held in granting motions to dismiss. *See, e.g.*, *In re Effexor XR Antitrust Litig.*, Civil Action No. 11-5479 (PGS) (LHG), 2014 WL 4988410, at *23–24 (D.N.J. Oct. 6, 2014); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389 (PGS), 2014 WL 4543502, at *22–23 (D.N.J. Sept. 12, 2014). The FTC is required to give the Court a reliable

foundation to assess the size and nature of the payment, but it has not done so. Instead, the FTC's allegations are again based on the assumption that AbbVie knew that Teva would not otherwise be able to come to market—an allegation the FTC does not (and cannot) make. The FTC has no plausible allegations for why this option supply agreement is unexplained, or how any payment under it (and again, the only payment would be from Teva to AbbVie) was "large." This failure is an independent basis to dismiss the FTC's complaint.

Third, the FTC's complaint fails because it does not plausibly allege that the AndroGel settlement agreement caused any anticompetitive effect. The key point here is that Teva's AndroGel product, unlike the products at issue in *Actavis* and the cases that have followed, is not a *generic* drug. Teva's AndroGel product was determined by the FDA *not* to be "therapeutically equivalent" to AbbVie's AndroGel product. As a result, Teva's AndroGel product would not (and could not) be automatically substituted for AbbVie's AndroGel, unlike the products at issue in *Actavis* and all of the cases applying *Actavis* to date. Unlike in those cases, the FTC's claim here depends on a series of implausible assumptions—not only that Teva would have marketed a product with little chance of profit, but that physicians would have prescribed Teva's unknown, non-substitutable AndroGel product instead of AbbVie's well-known and heavily marketed AndroGel, or an actual generic substitute for that product. The FTC can plead no facts to support this theory, and it is far too speculative to support a claim.

At bottom, the FTC is trying to expand the law to a category of settlement that bears no resemblance to what was addressed in *Actavis*—and did not plausibly lead to any competitive harm. Unlike in *Actavis*, this case does not involve a generic drug that would automatically be substituted for the branded product. There is no allegation of a payment of tens or hundreds of millions of dollars from the patent holder to the patent challenger. The alleged "reverse payment" here in fact

increased competition and *benefited* consumers by getting a competing product on the market faster. And the FTC cannot allege any plausible link between the TriCor supply option agreement and the alleged "delay," especially given the nearly identical Perrigo settlement that did not involve any other business agreement and resulted in [redacted].

The FTC's complaint fails as a matter of law and should be dismissed. As the complaint is a product of a lengthy investigation, there is no reason to grant the FTC leave to re-plead. The complaint should be dismissed with prejudice.

BACKGROUND

A. Regulatory Background

This case arises at the intersection of federal patent law and the complex statutory and regulatory scheme governing the production and marketing of pharmaceutical products—the Hatch-Waxman Act. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355) (amending the Federal Food, Drug, and Cosmetic Act ("FD&C Act")). Hatch-Waxman addresses the patent rights of innovator companies, often called "brand manufacturers," and encourages competition by generic manufacturers for pharmaceutical products. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). Hatch-Waxman recognizes the patent rights (including exclusivity) of brand manufacturers by permitting early patent challenges to proposed competing versions of their drug products (and by providing additional potential exclusivities to companies that develop innovative drugs). Simultaneously, the Act streamlines generic manufacturers' ability (1) to seek regulatory approval of generic drugs, and (2) to challenge brand manufacturers' pharmaceutical patents and thereby try to establish that the company can lawfully introduce its competing product.

1. Pathways For Product Approval Under Hatch-Waxman

FDA approval is required before any drug may be offered or sold. 21 U.S.C. § 331(d). As relevant here, FDA law creates three different pathways for approval of prescription drugs. A brand manufacturer seeking to introduce a new drug must submit a New Drug Application ("NDA") under Section 505(b)(1) of the FD&C Act to obtain FDA approval. The FDA will not approve an NDA until the applicant demonstrates that the drug is safe and effective for its intended use(s). *Id.* § 355(b)(1).

A company seeking to manufacture and sell a generic drug typically does not need to submit a full NDA. In most cases, the generic manufacturer may submit an Abbreviated New Drug Application ("ANDA"), which relies on the NDA's safety and efficacy results and is required to demonstrate that the proposed generic is "bioequivalent" to an approved branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(ii) & (iv). A product submitted and approved under an ANDA will be almost an exact copy of the referenced brand drug.

In other circumstances, a manufacturer seeking to introduce a competing version of an already-approved drug product may not be permitted to file an ANDA, and may instead be required to submit an NDA under Section 505(b)(2) of the FD&C Act. 21 U.S.C. § 355(b)(2). For example, a 505(b)(2) application is required when the applicant drug has a different dosage form, strength, formulation, or route of administration. The FDA also requires a 505(b)(2) application even if the drug is "essentially a duplicate," if it contains differences from the listed brand product such that "the type(s) of studies needed to support the differences between the proposed product and the listed drug (*e.g.*, differences in certain inactive ingredients) are outside the scope of what can be appropriately reviewed" through the ANDA process. *See* Letter from FDA to D. Himmelfarb et al. at 4 (July 23, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-0371-0006 (emphasis omitted); *see also* Compl. ¶¶ 77, 85.

2. Patent Certifications And Patent Litigation Under Hatch-Waxman

A brand manufacturer is required to identify patents covering the drug in its NDA. The FDA lists the patents in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e). If the Orange Book lists patents covering the relevant branded drug, an applicant submitting an ANDA or a 505(b)(2) application must also "assure the FDA that its proposed generic drug will not infringe the brand's patents." *Caraco*, 132 S. Ct. at 1676. An applicant can do this by filing a "[P]aragraph IV certification," which is a certification that the applicant believes that the brand manufacturer's patent is invalid or is not infringed by the proposed product. 21 U.S.C. § 355(b)(2)(A)(iv); *Caraco*, 132 S. Ct. at 1677. The applicant must notify the patent holder that it has filed a Paragraph IV certification and the basis for the challenge. 21 U.S.C. § 355(b)(3). To streamline such patent challenges and to allow a judicial determination on the merits of the patent challenge before any infringing sales (which may risk substantial infringement damages), Hatch-Waxman treats the filing of a Paragraph IV certification as a technical act of patent infringement, which permits the brand manufacturer immediately to bring an infringement action. *Caraco*, 132 S. Ct. at 1677 (citing 35 U.S.C. § 271(e)(2)(A)). In many cases, the applicant responds by filing a counterclaim asserting that the patent is invalid or unenforceable. Such litigation, like all patent litigation, is expensive and uncertain in outcome.

3. The FDA Determines Whether A Drug Is "Equivalent" And May Be Automatically Substituted For A Branded Product

The FDA has created a ratings system to grade a drug's "therapeutic equivalence" to the branded drug for which it seeks to be a substitute. For drug products "that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products," the FDA assigns an "A" rating. Orange Book at xiii (34th ed. 2014) (emphasis omitted). This grouping includes the "AB" rating, which indicates that any "actual or potential bioequivalence problems have been resolved

with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence." *Id.*; *see also id.* at xv–xvi. "FDA believes that [AB-rated drugs] can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product." *Id*. at vii. Drugs approved under an ANDA typically are given an AB rating.

By contrast, drugs approved under a 505(b)(2) application may or may not receive an AB rating. For drug products "that FDA at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products," the FDA assigns a "B" rating. *Id.* at xiii (emphasis omitted). This includes "drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence." *Id.* One such rating is the "BX" rating, which indicates that "the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence," and "the drug products are presumed to be *therapeutically inequivalent* until the Agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence." *Id.* at xx (emphasis added).

The difference between an AB rating and a BX rating is significant. The well-recognized ability of generic drugs to capture substantial sales upon launch, *see Actavis*, 133 S. Ct. at 2228–29, derives from the ability of pharmacists to dispense automatically those drugs as generic substitutes for the brand equivalent. "Today, all states facilitate competition through laws that allow a pharmacist to substitute an AB-rated generic drug when presented with a prescription for its brand equivalent, unless a physician directs or the patient requests otherwise." FTC's Br. as Amicus Curiae at 6, *Mylan Pharms., Inc. v. Warner-Chilcott Pub. Ltd. Co.*, No. 12-3824 (E.D. Pa. Dec. 3, 2012), 2012 WL 7649225. Under state law, however, pharmacists are not permitted to dispense as a substitute a drug that is *not* equivalent. Indeed, the great majority of states follow the Orange Book's classifications, or have requirements that mirror the Orange Book's classifications, in directing when

pharmacists may or must substitute a generic drug. *See* Jesse C. Vivan, *Generic Substitution Laws*, U.S. Pharmacist (June 19, 2008), *available at* http://www.uspharmacist.com/content/s/44/c/9787 (last visited Nov. 10, 2014) (collecting state laws).

This has serious ramifications for the viability of a non-AB rated drug in the market. As the FTC has explained, because a non-AB rated drug will not receive sales unless specifically prescribed by a physician and because the cost of the necessary marketing would likely exceed any profits, "[a]s a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product *disappears*." FTC's Br. as Amicus Curiae at 9, *Mylan Pharms. Inc.*, 2012 WL 7649225 (emphasis added). For these reasons, a drug that does not obtain an AB rating is not a "generic" at all. *See* Compl. ¶ 77 (noting that, absent an A rating, "the generic product would not be automatically substitutable for [the brand product]").

B. Case Background

This action arises out of a decision by AbbVie and Teva to settle their patent case rather than risk costly litigation with an uncertain outcome.[2]

[2] The statements set forth herein are taken from the FTC's complaint, from documents incorporated by reference or integral to the complaint, or from documents with respect to which the Court may take judicial notice. This includes the relevant agreements between AbbVie entities and Teva filed today with Defendants' unopposed sealing motion. *See* 12/20/11 Binding Term Sheet re AndroGel ("AndroGel Term Sheet," Ex. 1); 3/26/2012 Settlement and License Agreement ("AndroGel Settlement," Ex. 2); 12/20/11 Binding Term Sheet (Fenofibrate 48 mg and 145 mg) ("TriCor Term Sheet," Ex. 3); 5/10/12 Supply and Distribution Agreement ("TriCor Supply Option Agreement," Ex. 4); 12/20/11 Settlement and License Agreement ("Simcor Agreement," Ex. 5). These documents, which form the basis of the FTC's allegations and are described and referred to throughout the complaint, are properly referenced by the Court in deciding this motion to dismiss. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (holding that a court may consider documents upon which the complaint is "based"); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (same); *Sarpolis v. Tereshko*, Civil Action No. 13-5521, 2014 WL 2765088, at *1 n.4 (E.D. Pa. June 17, 2014) (same); *see also City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 259 (3d Cir. 1998) (considering "documents pertaining to the regulatory proceedings that are at the heart of the instant controversy" in granting a motion to dismiss). Although well-pleaded allegations in the complaint are accepted as true for purposes of this motion, Defendants contest many of them.

1. AbbVie's NDA For AndroGel

In April 1999, AbbVie submitted an NDA seeking approval to market a new drug called AndroGel 1% ("AndroGel"), a topical skin treatment indicated for testosterone replacement therapy in males who suffer from low testosterone levels. Compl. ¶¶ 36–38. AbbVie had previously obtained a license for the U.S. rights from Besins, AndroGel's manufacturer. *Id.* ¶ 37. The FDA approved the application in early 2000, and AbbVie launched AndroGel in June of that year. *Id.* ¶ 38. AbbVie and Besins also obtained a patent covering the use of pharmaceutical gel formulations containing testosterone and other ingredients in certain amounts—U.S. Patent No. 6,503,894 (the "'894 patent"). *Id.* ¶¶ 45, 58. The '894 patent covers testosterone gel that uses a specific penetration enhancer known as isopropyl myristate (IPM). *Id.* ¶¶ 45–46. The '894 patent does not expire until August 2020. *Id.* ¶ 59. Pursuant to FDA regulations, AbbVie listed the '894 patent in the Orange Book as claiming AndroGel. *Id.* ¶ 59; 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e).

AbbVie and Besins brought four suits asserting the '894 patent against companies seeking to sell competing versions of AndroGel. Each of the suits was resolved through settlement. In 2003, AbbVie asserted the '894 patent against Watson Pharmaceuticals (which later changed its name to Actavis), Par Pharmaceutical Companies, Inc., and Paddock Laboratories, Inc. after those companies sought approval for generic products under ANDAs. Compl. ¶ 73. Those suits were settled in 2006, after three years of hard-fought litigation. In each settlement, AbbVie and Besins licensed the generic company to market its AB-rated generic AndroGel product well before the patent expired in 2020. AbbVie also purchased marketing ("co-promotion") services and back-up supply services from Watson and Par. In a separate case pending in the Northern District of Georgia, the FTC has challenged these settlements as containing unlawful "reverse payments." *See In re AndroGel Antitrust Litig. (No. II)*, 888 F. Supp. 2d 1336, 1341–42 (N.D. Ga. 2012).

Two other manufacturers, Perrigo Company plc and Defendant Teva, sought FDA approval to market versions of AndroGel. The versions proposed by Perrigo and Teva used different penetration enhancers than AbbVie's AndroGel product. Compl. ¶¶ 61–63. Instead of IPM, Perrigo's product used isostearic acid (ISA) and Teva's used isopropyl palmitate (IPP). *Id.* Teva and Perrigo filed ANDAs for their respective products in 2008. AbbVie filed a petition with the FDA arguing that a company seeking to market such an AndroGel product should have to file a 505(b)(2) NDA—not an ANDA—due to the potential differences among penetration enhancers. *Id.* ¶ 69. The FDA granted the petition in significant part, refused to accept the ANDAs, and Perrigo and Teva were required to use the 505(b)(2) NDA process to obtain approval for their products. *Id.* ¶¶ 70–71.

2. Teva Obtains An Early-Entry License For AndroGel, But Its Product Is Not Given An AB Rating That Would Allow For Generic Substitution.

Teva submitted its 505(b)(2) NDA in early 2011, and filed a Paragraph IV certification that its product did not infringe the '894 patent. *Id.* ¶¶ 79–80. AbbVie filed a patent infringement suit against Teva on April 29, 2011, in the U.S. District Court for the District of Delaware, and Teva filed counterclaims. *Id.* ¶¶ 81, 83. *See generally Abbott Prods., Inc. v. Teva Pharm. USA, Inc.*, No. 1:11-cv-00384-HB (D. Del.). At the outset, Teva filed a motion for summary judgment for non-infringement based on prosecution history estoppel, and opposed AbbVie's requests for discovery. Compl. ¶ 84. The court rejected both of Teva's positions, ordering discovery to commence and setting the case for trial. *Id.* ¶ 84; Hr'g Tr. at 75, *Abbott Prods., Inc. v. Teva Pharm. USA, Inc.*, No. 1:11-cv-00384-HB (D. Del. Oct. 14, 2011). Following this Order, which denied Teva's attempt for an immediate resolution of the case, the parties sought to avoid the uncertainty and expense of a trial and ultimately settled the AndroGel patent litigation on December 20, 2011. The parties entered into a binding term sheet, which was later reflected in a settlement agreement. *See* Ex. 1 (AndroGel

Term Sheet); Ex. 2 (AndroGel Settlement). As part of the settlement, AbbVie granted Teva a license to sell Teva's AndroGel product beginning [redacted] before the expiration of the '894 patent. Compl. ¶¶ 59, 116; AndroGel Settlement at 5. This settlement agreement did not provide for any payment to Teva.

The FDA approved Teva's NDA for its AndroGel product on February 14, 2012. *Id.* ¶ 85. Importantly, the FDA did not assign the product an AB rating. *Id.* Rather, for more than two years, the FDA gave Teva's product no therapeutic equivalence rating at all—which is functionally the same as a determination that Teva's product was not equivalent to branded AndroGel. *Id.* Then, in July 2014, the FDA assigned the product a BX rating, *id.*, meaning the product in the FDA's view was "therapeutically inequivalent" and could not be automatically substituted for AndroGel. Orange Book at xx. At no time, then, has Teva's product been eligible for automatic generic substitution. As the FTC itself has stated, while Teva could "attempt to market a non-substitutable generic product directly to prescribing physicians, such a costly undertaking undermines the ability . . . to offer the lower price benefits that the federal and state regulatory framework was intended to foster." FTC's Brief as Amicus Curiae at 9, *Mylan Pharms. Inc.*, 2012 WL 7649225.

Teva also entered into two other agreements with AbbVie entities on December 20, 2011. Compl. ¶ 117; Exhibits 3, 5. One of these deals concerned the cholesterol drug TriCor (fenofibrate). Compl. ¶¶ 113, 117. Teva and Abbott Laboratories had previously settled patent litigation between them regarding TriCor, and agreed on an early-entry license that permitted Teva to sell a generic TriCor product on July 1, 2012. *Id.* ¶ 114. On December 20, 2011, Abbott Laboratories and Teva agreed that Teva would have the option of obtaining additional TriCor supply from Abbott Laboratories beginning several months later, in November 2012. *Id.* ¶ 117; *see also* Ex. 3 (TriCor Term Sheet) at 5–6. In exchange, Teva would pay [redacted]

[redacted] Compl. ¶ 117. Such option supply agreements are not uncommon, as they provide flexibility to manufacturers should a drug product exceed its initial sales expectations. The parties later finalized the term sheet in a supply agreement dated May 10, 2012. Ex. 4 (TriCor Supply Option Agreement). The November 10, 2012 date on which Teva was permitted to begin selling the TriCor supplied pursuant to the agreement was seven weeks before the date that AbbVie had licensed other generic manufacturers of TriCor to begin selling their products, and four months after the date on which Teva was licensed to launch its generic TriCor product under the prior settlement with AbbVie. Compl. ¶¶ 114–15.

Although Teva believed in December 2011 that obtaining FDA approval for its TriCor ANDA was unlikely, the FTC does not allege that AbbVie knew this fact, or knew whether Teva had an alternative source of TriCor supply, at the time it signed the binding term sheet. Nor could the FTC amend its complaint to make such an allegation, because the FTC knows from its investigation and public documents that AbbVie did not know about Teva's problems with TriCor until *after* the binding term sheet was signed and Teva made the disclosure on an investor call.[3] Teva ultimately did not receive final approval for its TriCor ANDA. On November 16, 2012, Teva launched its version of TriCor supplied by AbbVie, pursuant to the supply agreement. *Id.* ¶ 129. Under the terms of their respective licenses with AbbVie, other generic manufacturers also began selling generic TriCor products on this date. *Id.* By making it possible for Teva to launch generic TriCor in November 2012, therefore, the option supply agreement gave consumers earlier access to generic

[3] Teva Pharmaceutical Industries' CEO Discusses 2012 Business Outlook—Conference Call Transcript (Dec. 21, 2011) ("December 21, 2011 Conference Call"), *available at* http://seekingalpha.com/article/315378-teva-pharmaceutical-industries-ceo-discusses-2012-business-outlook-conference-call-transcript?part=single ("I just want to clarify on Tricor. Tricor is not, and I repeat is not in our 2012 work plan. We do not anticipate approval of our file in 2012 . . . .")

TriCor. Moreover, with Teva's entry, numerous other competitors entered the market earlier than they otherwise would have, which drove consumer prices down even further. *Id.* ¶¶ 121, 127–29.

Also on December 20, 2011, in another agreement (not mentioned by the FTC's complaint) Teva resolved ongoing patent litigation with different AbbVie entities (Abbott Laboratories and Abbott Respiratory LLC) regarding the drug Simcor. Pursuant to that settlement, Teva obtained an early-entry license to market a generic Simcor product [redacted] Ex. 5 (Simcor Settlement), at 4, 7.[4]

3. Perrigo Settles For The Same Early-Entry Date, And Obtains Approval For An AB-Rated AndroGel Product.

Teva was not the only company seeking approval to market a competing version of AndroGel. Perrigo also filed a 505(b)(2) NDA and Paragraph IV certification in late 2011 and was sued by AbbVie for patent infringement. Compl. ¶¶ 86–88. AbbVie, Besins, and Perrigo settled their patent litigation on December 8, 2011, approximately two weeks before AbbVie, Besins, and Teva settled their litigation. *Id.* ¶ 136. As the FTC recognizes, AbbVie, Besins, and Perrigo negotiated a settlement that provided nothing more than a compromise date of entry and [redacted]. *Id.* ¶¶ 134, 136. The FTC does not allege, and cannot allege, that the AbbVie, Besins, and Perrigo settlement contained a "reverse payment." Even so, Perrigo agreed with AbbVie to a license entry date of [redacted]—with a clause that allowed Perrigo to enter earlier should another manufacturer (such as Teva) receive an earlier license entry date or enter with a competing product. *Id.* ¶ 136. Perrigo's product received FDA approval on January 31, 2013. *Id.* ¶ 90. Unlike Teva's

[4] The FTC names Besins in Count I, but not in Court II, of the complaint. Besins was not a party to either the TriCor or Simcor agreements between AbbVie and Teva, and FTC does not (and cannot) allege that Besins was aware of either agreement.

product, Perrigo's product ultimately received the valuable AB rating that makes it automatically substitutable for branded AndroGel. *Id.*

C. The FTC's Challenge To The Settlement Agreement

Although the AndroGel settlement involved no payments from AbbVie to Teva, and permitted Teva to market a version of AndroGel [redacted] than if Teva had litigated the patent case and lost, the FTC nonetheless investigated the settlement. The FTC then brought this lawsuit, but with two of the five FTC commissioners voting *against* bringing the case—the first non-unanimous vote in a Hatch-Waxman patent settlement case.[5] This motion to dismiss follows.

LEGAL STANDARD

To survive a motion to dismiss, the FTC's complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)); *see also In re Effexor XR Antitrust Litig.*, Civil Action No. 11-5479 (PGS) (LHG), 2014 WL 4988410, at *14–15 (D.N.J. Oct. 6, 2014) (granting motion to dismiss); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389 (PGS), 2014 WL 4543502, at *14–15, *25 (D.N.J. Sept. 12, 2014) (same). Satisfying this burden "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555; *see also Iqbal*, 556 U.S. at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."); *Pearson v. Tanner*, 870 F. Supp. 2d 380, 382 (E.D. Pa. 2012) ("[T]he Court need not accept as true unsupported conclusions and unwarranted inferences or the plaintiff's bald assertions or legal

[5] *See* Press Release, FTC, *FTC Sues Pharmaceutical Companies for Illegally Blocking Consumer Access to Lower-Cost Versions of the Blockbuster Drug AndroGel* (Sept. 8, 2014), *available at* http://www.ftc.gov/news-events/press-releases/2014/09/ftc-sues-pharmaceutical-companies-illegally-blocking-consumer; *see also Kos Pharmaceuticals, Inc. v. Andrx Corp.*, 369 F.3d 700, 705 n.5 (3d Cir. 2004) (holding that documents found on an agency's website are judicially noticeable as "public records").

conclusions.") (citations and internal quotation marks omitted), *aff'd*, 513 F. App'x 152 (3d Cir. 2013).

As the Supreme Court recognized in *Twombly*, "antitrust discovery can be expensive," and "it is only by taking care to require allegations that reach the level suggesting [a violation] that we can hope to avoid the potentially enormous expense of discovery in cases with no reasonably founded hope that the [discovery] process will reveal relevant evidence" to support a claim. 550 U.S. at 558–59 (second brackets in original) (citation and internal quotation marks omitted). "[S]ome threshold of plausibility must be crossed at the outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase." *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003) (Posner, J.) (quoted in *Twombly*, 550 U.S. at 558). A complaint that fails as a matter of law should be dismissed "at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (citation and internal quotation marks omitted); *see also Effexor*, 2014 WL 4988410, at *15, *26; *Lipitor*, 2014 WL 4543502, at *15, *25.

ARGUMENT

The FTC unsuccessfully attempts to turn a routine, and procompetitive, patent litigation settlement into an antitrust violation. This attempt fails because there is nothing remotely unlawful about settling patent litigation with an early-entry license, as Defendants did here. The Supreme Court made clear in *Actavis* that settlements ending Hatch-Waxman patent litigation, like all other patent litigation settlements, do not typically raise antitrust concerns and, in fact, promote the longstanding policy in favor of the settlement of patent disputes short of trial. *FTC v. Actavis*, 133 S. Ct. 2223, 2234, 2237 (2013). The Court in *Actavis* set forth a narrow exception to this general rule, applicable only to settlements that contain a so-called "reverse payment," that is a payment *from* the patent holder (the brand company) *to* the alleged infringer (the generic company) to compensate the

generic for the period of time the generic is not on the market selling a competing product. 133 S. Ct. at 2227. That reverse payment must also be "large" and "unexplained" and must "bring with it the risk of significant anticompetitive effects." *Id.* at 2236–37. Only when a complaint adequately alleges such a reverse payment can those facts override "the desirability of settlements." *Id.* at 2237.

To state a claim under *Actavis*, the FTC must allege: (1) the settlement contained a "payment"; (2) the payment is a "reverse payment," *i.e.*, the payment must be from the patentee to the alleged infringer; (3) the payment must be "unexplained" by "traditional settlement considerations"; *and* (4) any unexplained portion of the payment must be "large," with the complaint providing sufficient detail on how to value the payment so that the court can make this determination. *Id.* at 2236–37; *Lipitor*, 2014 WL 4543502, at *13, *22; *Effexor*, 2014 WL 4988410, at *16–18; *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995 (WHW), 2014 WL 282755, at *5 (D.N.J. Jan. 24, 2014); *In re Loestrin 24 FE Antitrust Litig.*, MDL No. 13-2472-S-PAS, 2014 WL 4368924, at *7–9 (D.R.I. Sept. 4, 2014). The FTC must satisfy *all four* of these elements, and here it can satisfy none. Moreover, the FTC has made no plausible allegations that the alleged conduct here caused any "significant" anticompetitive harm. Nor could it, as Teva's product is not "therapeutically equivalent" to AbbVie's AndroGel product and thus is not a substitute in the marketplace.

No amount of creative legal advocacy can mask the glaring holes in the FTC's allegations. Its complaint fails as a matter of law and should be dismissed in its entirety as to Teva, and to the extent that it challenges the AndroGel settlement as to the other defendants.

I. The FTC Does Not Properly Allege An Actionable "Reverse Payment" Under *Actavis*.

The FTC's complaint fails first and foremost because it alleges no payment, and certainly no "reverse payment," that would give rise to a claim under *Actavis*. The Supreme Court made clear in *Actavis* that the only settlements that potentially raise antitrust concerns are those involving a

"payment" *from* the patent holder (the brand company) *to* the alleged infringer (the generic company) to compensate the generic for the period of time the generic is not on the market selling a competing product. As the Supreme Court stated in the first paragraph in *Actavis*, it was addressing the situation where "Company A, the patentee, [agrees] to pay [Company B, the claimed infringer,] many millions of dollars," "rather than the other way around." 133 S. Ct. at 2227; *see also id.* at 2229 (describing allegations of payments ranging from $12 million to $200 million). The FTC has not made any such allegation here. Instead, the FTC asks this Court to expand *Actavis* beyond the bounds set by the Supreme Court. The FTC seeks to impose antitrust liability on parties that entered into a procompetitive, early-entry patent settlement agreement and a procompetitive supply agreement, both of which got lower-priced drugs to consumers more quickly. But the combination of two procompetitive agreements is not a "reverse payment" and is not actionable.

A. The AndroGel Settlement Contains No Payment At All And Instead Provides Only For An Early-Entry License.

The AndroGel settlement contains no payment at all. The AndroGel settlement gives Teva only an early-entry license that allows it the opportunity to introduce a competing AndroGel product nearly [redacted] the relevant patents on the drug expire. Compl. ¶¶ 59, 116; Ex. 2 (AndroGel Settlement) § 3.1. In agreeing to settle their expensive and risky patent litigation, AbbVie, Besins, and Teva compromised on the date the early-entry license would begin—not immediately (in 2012), and not at the end of the patent term (in 2020), but rather somewhere in the middle.

This is precisely the type of settlement agreement that the Supreme Court has held does *not* give rise to further scrutiny, much less liability, under the FTC Act. *Actavis*, 133 S. Ct. at 2233. The Court expressly held that litigating parties in a Hatch-Waxman case "may, as in other industries, settle . . . by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 2237;

accord Lamictal, 2014 WL 282755, at *5 ("[T]he Court explicitly created a carve out for early entry provisions . . . ."). As the Court recognized, such agreements enable *more* competition, not less. *See Actavis*, 133 S. Ct. at 2234 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit."); *see also id.* at 2230–32 (citing decades of precedent holding that a patent holder may grant a license to practice its patent).

The FTC argued in *Actavis*, and has argued in other cases, that parties may and *should* settle patent litigation exactly as the parties did here, with an early-entry license. The FTC told the Supreme Court that "the parties to paragraph IV litigation *have broad freedom* to settle by agreeing upon a *compromise date* of generic entry." Reply Br. for Pet'r at 8–9, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 1099171 (emphasis added). The FTC made clear that such agreements do not raise antitrust concerns: "[A] compromise date of market entry is a natural and generally lawful term of an agreement to settle patent litigation." *Id.* at *9 (emphasis omitted). The FTC has taken this position consistently for nearly a decade. *See, e.g.*, FTC's Pet. for Writ of Cert. at 17–18, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2105243 ("[S]ettlements that are beneficial or neutral to consumers are certainly possible. For example, if the parties simply compromise on an entry date prior to the patent's expiration, without cash payments, the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent."). Here, the parties did just what the FTC said they should do—settle with a "compromise date." There was no payment in the AndroGel settlement, dooming the FTC's complaint as a matter of law.

B. The Only "Payment" Alleged By The FTC Is Not An Actionable "Reverse Payment."

Knowing this, the FTC tries to manufacture a payment where none exists. The FTC argues that the so-called "payment" in this case was a separate agreement between Teva and another AbbVie-related entity, in which Teva obtained the option of acquiring supply of a different product—TriCor. This argument fails. The FTC does not allege facts making it plausible that the TriCor supply option agreement was a "reverse payment" under *Actavis*, nor does the FTC allege facts to make it plausible that, but for the TriCor supply option agreement, AbbVie would have agreed to an earlier entry date for Teva's AndroGel product.

1. The TriCor Supply Option Agreement Is Not A "Reverse Payment" Under *Actavis* As A Matter Of Law.

The FTC's claim depends on the existence of a "reverse payment"—without a "reverse payment," there is no actionable antitrust claim. After all, "courts have long recognized that merely because a settlement is of some value (even of great value) does not mean that it constitutes a reverse payment." *Loestrin*, 2014 WL 4368924, at *10 (granting motion to dismiss for lack of a reverse payment); *see also Lamictal*, 2014 WL 282755, at *6, *8 (granting a motion to dismiss because the challenged settlement contained no reverse payment). "If any settlement agreement is . . . classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements."*Asahi Glass*, 289 F. Supp. 2d at 994.

The Supreme Court made clear in *Actavis* what it meant by "reverse payment"— payment to the generic manufacturer to compensate it for the period of time it is not on the market with a competing product. 133 S. Ct. at 2233 (describing a reverse payment settlement as one where "a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market"); *id.* at 2234 ("payment in return for staying out of the market"). In *Actavis*, for example, the FTC alleged that the patent holder paid more than $200 million to the generic

manufacturers during the period of time the generic manufacturers were not on the market with a competing product. *Id.* at 2229. The FTC alleged that the business services provided by the generic manufacturers in exchange for those payments were shams, meaning the payments were used only to "pay for delay." *Id.*

There was no such payment here. The TriCor supply option agreement involves no payments to Teva. On the contrary, the option supply agreement provides for a payment of royalties *from* Teva *to* AbbVie in exchange for product—which is exactly how supply agreements are expected to work. There is nothing "reverse" about this flow of consideration. Nor did Teva make money by "stay[ing] out of [the] market," which is the concern addressed by the Supreme Court in *Actavis*. 133 S. Ct. at 2231. Under both the TriCor supply option agreement and the AndroGel settlement agreement, the only way in which Teva would make any money would be by selling a competing, lower-priced drug to consumers. This is undeniably *procompetitive*, and does not meet the criteria for a reverse payment. "In a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market." *Asahi Glass Co.*, 289 F. Supp. 2d at 994. In contrast, where "there is only a 'payment' to the settling defendant when competition breaks out," then "the settlement led to increased competition." *Id.* The TriCor supply option agreement thus in no way resembles the alleged "reverse payments" described by the Supreme Court in *Actavis*: It did not involve a payment of money to stay off of the market, but rather an agreement to accelerate generic entry from the end of the patent term. 133 S. Ct. at 2229.[6]

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[6] The settlement challenged here also is nothing like those at issue in post-*Actavis* cases that have survived motions to dismiss. In denying the motion to dismiss in *Niaspan*, for example, the court relied on the allegation that the settlement in that case included cash payments to the generic challenger as part of business deals—but the payments were made only "as long as [the generic company] kept its generic equivalent of Niaspan off the market." *In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 WL 4403848, at *12 (E.D. Pa. Sept. 5, 2014). Likewise, in *Nexium*, the court found that there was "a steady flow of revenue to Ranbaxy … in the precise time period during which it agreed to refrain from marketing its generic Nexium product." *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY, 2014 WL 4370333. at *24 (D. Mass. Sept. 4, 2014). In other words, the generic company was alleged to have been paid

The FTC's allegations show that *both* the AndroGel settlement *and* the TriCor supply option agreement were procompetitive. Combining two procompetitive agreements cannot be the basis for an antitrust violation. Both agreements gave Teva the prospect of launching a competing drug and selling that lower-priced product to consumers *before* it otherwise could have done so. For AndroGel, the license gave Teva a guaranteed [redacted] of entry before the relevant patent expired. For TriCor, the option supply agreement allowed Teva to launch a TriCor product when it otherwise likely could not have—although the FTC does not allege that Teva's problems were known to AbbVie at the time—and approximately seven weeks before other generic competitors were expected to enter. The agreement thus undeniably benefited purchasers of TriCor.

Against all logic, the FTC argues that the procompetitive AndroGel settlement and the procompetitive TriCor supply option agreement, when added together, somehow equal an antitrust violation. This arithmetic does not work. *Cf. Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 457 (2009) ("Two wrong claims do not make one that is right."). An agreement that *creates* additional competition cannot violate the FTC Act. As the Third Circuit has stated, "[e]nhancement of consumer choice is a traditional objective of the antitrust laws," and an agreement that "actually enhances consumer choice" is "beyond the scope" of the antitrust laws. *United States v. Brown Univ.*, 5 F.3d 658, 675–77 (3d Cir. 1993); *see also Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 779–80 (1999) ("[T]he essential inquiry [is] whether or not the challenged restraint enhances competition.") (citation and internal quotation marks omitted).

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cash as long as it did not sell its generic product. The FTC here has not alleged such a payment, so even assuming the cases are rightly decided (which defendants respectfully contest), *Niaspan* and *Nexium* are inapt.

2. The FTC's Argument That The TriCor Supply Option Agreement Was A "Reverse Payment" Depends On An Allegation The FTC Does Not Make.

Even assuming an agreement that creates early generic entry could, in some circumstances, be a "reverse payment" under *Actavis*, the FTC's claim depends on its argument that AbbVie's decision to enter into the TriCor supply option agreement "only makes sense as a means to induce Teva to drop its patent challenge," because Teva had no other supply option and no other means of coming to market with a competing TriCor product. Compl. ¶¶ 9, 114–15, 126. Thus, according to the FTC, this facially procompetitive agreement somehow became suspect because AbbVie was creating competition against itself for TriCor where otherwise there would have been no competition. *See id.* This argument fails because it depends on an allegation the FTC does not make—and cannot make: that at the time of the agreement AbbVie *knew* Teva would be unable to come to market absent the TriCor supply option agreement. Without such an allegation, there is no basis for treating the supply agreement as anything other than a legitimate business transaction, and the FTC's theory collapses.

As the FTC knows from its investigation and public documents (and the FTC's complaint does not dispute), AbbVie did not know about Teva's problems with TriCor until *after* the binding term sheets were signed on December 20, 2011. *See* Dec. 21, 2011 Conference Call, *supra* n.3. All the FTC alleges (and can allege) is that it was publicly known that Teva had not *yet* secured FDA approval for its generic TriCor products at the time of the settlement, Compl. ¶ 127. That allegation does not "nudge" the FTC's assertion that the supply agreement "does not make sense . . . as an independent business transaction," Compl. ¶ 9, "from conceivable to plausible," as required by *Twombly*. 550 U.S. at 570. The settlement occurred more than six months *before* the earliest date Teva could launch under the prior TriCor patent license agreement (July 2012), and the FDA did not need to act on the application until that date. *Id.* ¶ 114; *see Roxane Labs., Inc. v. SmithKline*

Beecham Corp., No. 09-CV-1638, 2010 WL 331704, at *4 (E.D. Pa. Jan. 26, 2010) (describing FDA approval as last step before sale of generic drug); *see also Twombly*, 550 U.S. at 557 (allegations must "raise[] a suggestion" of actionable conduct, not merely conduct that could "just as well be" lawful).[7]

The FTC thus has not pleaded facts that plausibly support its claim that the TriCor supply option agreement is a "sweetheart" deal that "facilitated generic entry on one of [AbbVie's] blockbuster drugs in November 2012, a month and a half earlier than generic entry was otherwise likely to occur" and "cannot be explained as an independent business deal from [AbbVie's] perspective." Compl. ¶¶ 125, 127; *see also id.* ¶ 115. Rather, the supply option agreement is no more than it purports to be—an unremarkable supply option agreement whereby a company (Teva) that is expected to launch TriCor in July 2012 obtained the option of acquiring additional supply of the product beginning a few months after launch, in case demand for the product exceeded its original supply options. For AbbVie, which naturally would have a lesser demand for branded TriCor after the generic launch of TriCor which was expected in July 2012, supplying a company such as Teva would allow AbbVie to utilize excess capacity. The FTC engages in extensive maneuvering to try to paint this straightforward business agreement as untoward, but it leaves out the allegation that is necessary for the theory to work—that AbbVie knew Teva could not otherwise

[7] The FTC does not (and could not) allege that the absence of a public approval for Teva's TriCor ANDA by December 2011 means—or could plausibly have been interpreted by AbbVie to mean—that Teva would never obtain approval. Indeed, even though a different ANDA for TriCor (filed by Lupin) had been pending for over three years and had not been approved by December 20, 2011, it was approved shortly thereafter. *See* Department of Health & Human Servs. Letter to Lupin Pharmaceuticals (Dec. 23, 2011) (http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/090856s000ltr.pdf. The Court may take judicial notice of these FDA records on a motion to dismiss. *See, e.g.*, *Stengel v. Medtronic Inc.*, 676 F. 3d 1159, 1167 (9th Cir. 2012) ("Because the accuracy of FDA records cannot reasonably be questioned, the premarket approval status of [the device] is a fact subject to judicial notice."), *rev'd en banc on other grounds*, 704 F.3d 1224 (9th Cir. 2013); *Horne v. Novartis Pharm. Corp.*, 541 F. Supp.2d 768, 777 (W.D.N.C. 2008) ("[T]he Court may take judicial notice of and consider the public records of the FDA . . . ."); *see also Pittsburgh v. W. Penn Power Comp.*, 147 F.3d 256, 259 (3d Cir. 1998) (considering "documents pertaining to the regulatory proceedings that are at the heart of the instant controversy" in affirming district court's granting of a motion to dismiss).

come to market.[8] The FTC cannot base its complaint on an allegation it does not make, especially where (as here) it knows, based on its investigation, that such an allegation would be false. *See, e.g.*, *Smith v. Sternes,* No. 02 C 50178, 2004 WL 1406142, at *1 (N.D. Ill. June 22, 2004) (dismissing case where plaintiff's equitable tolling theory depended on facts that she did not plead in her complaint); *Hamilton v. Wyeth*, No. 2:03CV00043GH, 2003 WL 24281166, at *2 (E.D. Ark. June 17, 2003) (dismissing case where plaintiff's constructive fraud theory depended on a particular statement being made, but plaintiff never alleged that the statement actually occurred); 2 *Moore's Federal Practice—Civil* § 8.04[2][c] (3d ed. 2014) (recognizing that a complaint is subject to dismissal "if there is no factual support for a crucial element of a claim"); *see generally Frederico v. Home Depot*, 507 F.3d 188, 204 (3d Cir. 2007) (affirming dismissal of claim where plaintiff "failed to provide allegations to support" the claim).

Nor can the FTC base an antitrust claim on an assertion that a procompetitive agreement was not procompetitive enough. The FTC argues that Teva should have gotten a "better" deal for consumers and obtained an even *earlier* entry date for its AndroGel license. But courts have long refused to second-guess the terms of licenses or hold that a settlement is anticompetitive simply because a plaintiff can imagine a more procompetitive settlement. *See, e.g.*, *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415–16 (2004) ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."); *La. Wholesale Drug Co. v. Shire LLC*, 929 F. Supp. 2d 256, 262 (S.D.N.Y. 2013) ("The mere fact that pricing for the public *could have been lower* under the terms of a particular settlement agreement does not mean that an antitrust violation results when that theoretical optimal result for consumers is not met."), *aff'd by In re Adderall XR*

[8] The FTC also does not have any theory for how the other deal between AbbVie and Teva during the same time period, the Simcor settlement agreement, fits into its reverse payment theory, further undermining the plausibility of that theory.

Antitrust Litig., 754 F.3d 128 (2d Cir. 2014); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 536 (E.D.N.Y. 2005) ("[I]f defendants were within their rights . . . in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable."); *see also Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163, 171 & n.5 (1931) (recognizing that "[w]here there are legitimately conflicting [patent] claims . . . , a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," even if the settlement is not the most procompetitive outcome).[9]

3. The FTC's Complaint Contains No Plausible Allegations Tying The TriCor Supply Option Agreement To A Later Entry Date For AndroGel.

Equally important, the FTC does not plausibly allege any link between the TriCor supply option agreement and an alleged "delayed" entry date for Teva's competing AndroGel product. This is a critical failure of the FTC's claim—after all, with no link between the TriCor supply option agreement and the license date for AndroGel, the FTC cannot prove that the TriCor supply option agreement was a "payment" made in exchange for Teva agreeing to "stay out" of the market. *Actavis*, 133 S. Ct. at 2237. The FTC cannot rely on allegations that raise the mere "possibility" that the TriCor supply agreement created delay; rather, the FTC must plead sufficient facts to make it "plausible" that Teva would have obtained a license date earlier than [redacted] had there been no alleged "reverse payment." *Iqbal*, 556 U.S. at 679; *Twombly*, 550 U.S. at 555–56.

The FTC's complaint fails this test. Indeed, the complaint demonstrates that any argument that Teva would have negotiated an earlier entry date on AndroGel but for the TriCor supply option agreement is the height of speculation. To be sure, the FTC makes the conclusory assertion that

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[9] The FTC's selective quotation of a letter sent by another drug company to Teva does not change the analysis. *See* Compl. ¶ 118. When read in context, the letter is nothing more than a negotiation tactic designed to extract a hefty sum (at least ten million dollars) from Teva, rendering any arguments in the letter unreliable, at best, and entitled to no weight by this Court. In any event, these out-of-court statements from a third party are inadmissible hearsay. *See* Fed. R. Evid. 801, 802; *Agere Sys., Inc. v. Advanced Envtl. Tech. Corp.*, 602 F.3d 204, 232 (3d Cir. 2010).

"Teva was willing to agree not to compete until [redacted] because [AbbVie] . . . compensated Teva" through the TriCor supply option agreement. Compl. ¶ 104; *see also id.* ¶ 115. But the facts as alleged by the FTC belie this claim.

First, as the FTC acknowledges in its complaint, another generic company (Perrigo) also challenged AbbVie's patent on AndroGel. *Id.* ¶¶ 86–88. Perrigo's product, like Teva's product, used a different penetration enhancer than AbbVie's AndroGel product. *Id.* Perrigo, like Teva, was required to file a 505(b)(2) application, rather than an ANDA. *Id.* ¶¶ 70–71. AbbVie sued Perrigo only months after AbbVie filed litigation against Teva. *Id.* ¶¶ 88, 134. Perrigo, like Teva, ultimately decided to avoid the risk and expense of uncertain patent litigation and to resolve the case via settlement. *Id.* ¶ 136. Perrigo, like Teva, negotiated a settlement with AbbVie and Besins that provided for a compromise entry date for a license to introduce its own AndroGel product. *Id.* Through negotiations, Perrigo and AbbVie agreed on an entry date of [redacted] *Id.* Perrigo has now obtained approval for its product and the FDA assigned it an AB rating, meaning it is a true generic that can automatically be substituted for branded AndroGel, unlike the Teva product. *Id.* ¶ 90.[10]

The FTC does not allege that the Perrigo settlement contains a reverse payment. In fact, the FTC knows there was no such payment because it had a right to review (and did review) the Perrigo AndroGel settlement under the terms of an unrelated Consent Order to ensure it did not contain a reverse payment. *See id.* ¶ 134. The FTC thus cannot plausibly contend that the TriCor supply

[10] The only other settlements of litigation regarding AndroGel and the '894 patent resulted in license dates [redacted] *See In re AndroGel Antitrust Litig. (No. II)*, 888 F. Supp. 2d 1336, 1339 (N.D. Ga. 2012) [redacted].

option agreement in any way influenced the date of the early-entry license in the Teva AndroGel settlement. AbbVie's litigation against Perrigo was filed only months after its litigation against Teva, *see id.* ¶¶ 81, 88, meaning the timing is similar. Perrigo also had an even greater incentive than Teva to market its product, as its product eventually obtained an AB-rating and thus had far greater earning potential than Teva's non-substitutable product. *Id.* ¶ 90. And it is undisputed that the Perrigo settlement does not contain any "reverse payment" influencing the license date, meaning that the agreed-upon entry date reflected nothing more than a compromise based on the parties' views of the patent and the market. *Id.* ¶ 134; FTC's Pet. for Writ of Cert. at 17–18, *Schering-Plough Corp.*, 548 U.S. 919, 2005 WL 2105243 ("[I]f the parties simply compromise on an entry date prior to the patent's expiration, without cash payments, the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent."). Nevertheless, the Perrigo settlement resulted in an entry date that [redacted]. Compl. ¶ 136. In other words, the settlement between Teva and AbbVie had *greater* consumer benefits than the settlement between Perrigo and AbbVie *even if one were to accept the FTC's unsupported assertion that the Teva settlement included a supply option agreement (while Perrigo's did not)*. As confirmed by the Perrigo settlement, the FTC's claim that the TriCor supply option agreement influenced the date of the Teva early-entry license for AndroGel is thus hardly "conceivable," let alone "plausible," and hence insufficient as a matter of law to defeat a motion to dismiss. *Twombly*, 550 U.S. at 570; *Iqbal*, 556 U.S. at 679; *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 319 (3d Cir. 2010).[11]

[11] The FTC's attempt to blame *Teva* for the Perrigo settlement borders on frivolous. Compl. ¶¶ 133-37. It was obviously Perrigo that entered into a settlement agreement to settle its litigation with AbbVie. Teva is not alleged to have even been aware of the Perrigo settlement when it settled its litigation. Perrigo certainly could have chosen to litigate and try to win the patent case, and its decision not to do so had just as much impact on the market for AndroGel as did Teva's decision. Indeed, given that Perrigo has an AB-rated product (*i.e.*, a true generic), its settlement had a far *greater* impact on the market than did Teva's settlement. The FTC has decided not to bring a claim against Perrigo, and it cannot backdoor such a claim by blaming the Teva-AbbVie settlement for the fact that Perrigo is not on the market.

Second, the economics of the pharmaceutical industry, as explained in *Actavis*, reinforce the implausibility of the idea that the supply option agreement for TriCor was consideration for a later AndroGel entry date. Central to *Actavis'* statement that "reverse payment settlements . . . can sometimes violate the antitrust laws" was the concept that the economics permit patentees to use such settlements to "share . . . monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 133 S. Ct. at 2227, 2235. "[T]he very anticompetitive consequence that underl[ay] the claim of antitrust unlawfulness" in *Actavis* was the maintenance of "supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* at 2236. But that economic framework is not present where the alleged payment for purportedly delayed marketing of one drug takes the form of enabling a generic company to compete earlier with a different drug. In this situation, there is no "shar[ing]" of "supracompetitive prices" whatsoever. And even if a plaintiff could speculate in *some* cases that a brand manufacturer might gain more from delayed entry of a generic for one of its drugs than it would be harmed by accelerated entry of a generic for another of its drugs (*e.g.*, if the allegedly accelerated drug had fewer potential competitors than the allegedly delayed drug), the FTC's complaint contains no such allegations. On the contrary, the FTC alleges that Teva's launch of generic TriCor "allow[ed] [other generic companies] to launch their own generic TriCor products" in competition with Teva. Compl. ¶ 129. This simply is not a situation in which it is "plausible" to conclude that there has been a potentially actionable "reverse payment." *Twombly*, 550 U.S. at 570; *Iqbal*, 556 U.S. at 679; *In re Ins. Brokerage*, 618 F.3d at 319.

II. The FTC's Complaint Fails Because It Does Not Adequately Plead That Any Alleged "Reverse Payment" Is Both "Unexplained" And "Large."

Even assuming, hypothetically, that the AndroGel settlement contained a reverse payment (and it did not), the FTC's complaint fails for the independent reason that it contains no plausible

allegations that any such payment was "unexplained" and "large"—*both* of which are required to state an *Actavis* claim. *Actavis*, 133 S. Ct. at 2237; *see also Effexor*, 2014 WL 4988410, at *16 (in "apply[ing] the *Twombly* and *Iqbal* standards against the factors of *Actavis*," the "court must determine whether there was a reverse payment that is large and unjustified"); *Lipitor*, 2014 WL 4543502, at *18 (holding that courts must "examine[] whether the factual allegations are sufficient to make plausible that [the brand company] made a *large* and *unexplained* reverse payment to [the generic company] in support of antitrust activities") (emphasis added); *Loestrin*, 2014 WL 4368924, at *7 ("In Step Two, a district court must ask, is that reverse payment large and unjustified?") (citation and internal quotation marks omitted). The reason for this is straightforward—*Actavis* does not apply merely because a settlement contains some consideration to the generic manufacturer. After all, *every* settlement (like every contract) necessarily involves consideration on both sides. The Supreme Court considered—and expressly rejected—the FTC's proposed rule that any Hatch-Waxman settlement with net consideration flowing to the generic company be deemed *per se* illegal or presumptively unlawful. *Actavis*, 133 S. Ct. at 2237. Instead, the Court upheld the general rule in favor of settlements and held that only certain settlements—those containing "reverse payments" that are "large" and "unexplained"— "sometimes" present antitrust concerns. *Id*.

As multiple courts have held since *Actavis*, the failure to make plausible allegations, based on facts, of a "large" and "unexplained" payment warrants dismissing the complaint. *See, e.g.*, *Effexor*, 2014 WL 4988410, at *22–23 (dismissing plaintiffs' alleged valuation as implausible because the complaint "provides no reliable foundation of this value or any explanation for the calculation of this amount"); *Lipitor*, 2014 WL 4543502, at *20–21 (rejecting plaintiffs' valuation figures as implausible because there was no "reliable foundation or methodology" alleged to support them);

Loestrin, 2014 WL 4368924, at *11 (dismissing complaint for failure to "plead[] facts sufficient to glean the monetary value of non-cash settlements").

A. The FTC Has Not Pleaded—And Cannot Plead—That Any Alleged Payment Received By Teva Is "Unexplained."

The FTC does not attempt to allege that the TriCor supply option agreement is unexplained from Teva's perspective. Nor could it, as the option supply agreement makes perfect sense for Teva as a legitimate free-standing business transaction that Teva would have undertaken even were it not settling the AndroGel litigation—providing Teva with a supply option for TriCor at a reasonable, bargained-for royalty rate.

Instead, the FTC argues that the TriCor supply option agreement "cannot be explained as an independent business deal from [AbbVie's] perspective." Compl. ¶ 125. Again, the FTC's entire argument on this score presumes that AbbVie knew that Teva could not otherwise bring a TriCor product to market. As explained above, however, the FTC does not allege this necessary fact, rendering all of the FTC's allegations on the "unexplained" prong a nullity. For example, the FTC alleges that "it is highly unusual for an authorized generic product to launch significantly before independent generic entry is expected," and that "[AbbVie] facilitated generic entry on [TriCor] in November 2012, a month and a half earlier than generic entry was otherwise likely to occur." *Id.* ¶¶ 126–27. But the Teva license for TriCor began in July 2012, months ahead of the November 2012 supply agreement date. *Id.* ¶¶ 114, 117. Absent an allegation that AbbVie knew Teva could not launch on July 2012, the only reasonable assumption is that AbbVie expected that Teva would have introduced a TriCor product at that time, months before Teva had the option to buy supply from AbbVie. The FTC also alleges that "[AbbVie's] payment took the form of product supply that was not otherwise available to Teva." *Id.* ¶ 120. Again, however, there is no allegation that AbbVie *knew* this at the relevant time—when the term sheet was signed on December 20, 2011. *See Valley*

Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1306 (11th Cir. 2003) ("We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into."), *abrogated on other grounds by Actavis*, 133 S. Ct. at 2230; *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 316–24 (3d Cir. 1998) (evaluating a settlement based on what the parties knew at the time it was entered into). The FTC does not allege that the agreement is "unexplained" from AbbVie's perspective if AbbVie did *not* know that Teva was not ready to bring its TriCor product to market in July 2012. This failure dooms the complaint.

B. The FTC's Conclusory Allegations Are Insufficient To State A Claim That Any Unexplained Payment Was "Large."

The FTC's complaint also fails for the independent reason that it does not plausibly allege that any "unexplained" portion of a "reverse payment" was "large." Simply calling the payment "large," as the FTC does throughout its complaint, *see, e.g.*, Compl. ¶¶ 104, 119, is insufficient. The FTC must plead *facts* that would allow the Court to determine whether the payment was indeed "large." *See Twombly*, 550 U.S. at 556–57, 570 (requiring "enough fact[s]," not mere "conclusory allegation[s]," from which to plausibly infer an antitrust violation).

This is especially critical in cases like this one, where the alleged "payment" is not a monetary payment, but rather unquantified consideration to the generic manufacturer. *See, e.g.*, *Effexor*, 2014 WL 4988410, at *22 (holding that asserting that the value of a non-monetary payment is large is insufficient and requiring allegations supporting a "reliable foundation" for valuing the payment); *Lipitor*, 2014 WL 4543502, at *22–23 (concluding that factual allegations were insufficiently pled regarding whether the supposed reverse payments were "large," leaving the court "unable to perform the analysis"); *Loestrin*, 2014 WL 4368924, at *11 (similar). As another district court in the Third Circuit stated in granting a motion to dismiss a "reverse payment" case, "the non-

monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors such as whether it is 'large' once the subtraction of legal fees and other services provided by generics occurs." *Lipitor*, 2014 WL 4543502, at *18, *23; *see also Effexor*, 2014 WL 4988410, at *20, *22–23 (holding that "[t]he pleading must show some reliable foundation for estimating the alleged reverse payment").

The FTC does not provide such a "reliable foundation" in this case. The only quantification the FTC provides is its allegation that "Teva forecasted that its net sales of authorized generic TriCor under the deal would be nearly $175 million over a four-year period" and that "Teva's actual generic TriCor sales have far exceeded this forecast, making the authorized generic deal worth hundreds of millions of dollars to Teva." Compl. ¶ 120. But, again, the relevant inquiry is what AbbVie knew at the time of the agreement, and the FTC does not allege that AbbVie knew that Teva could not otherwise come onto the market.[12] The question of how much Teva would make from TriCor is thus irrelevant, as AbbVie would have expected Teva to earn this regardless of the source of Teva's product. The relevant quantification is AbbVie's perception of the incremental value to Teva of having an *additional* option for TriCor supply beginning four months after Teva was expected to launch a generic TriCor product.

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12 This also dooms the FTC's allegation that the royalty rate Teva paid was "worse" than in "a typical stand-alone authorized generic agreement." Compl. ¶¶ 130–31. As an initial matter, in *Actavis*, the FTC conceded that an early entry license raises no antitrust concerns, whether it contains a royalty or not. Reply Br. for the Pet'r, *FTC v. Actavis*, No. 12-416, 2013 WL 1099171, at *12 (U.S. filed Mar. 18, 2013). That concession dooms FTC's argument here that the supply agreement gives Teva a royalty rate that is lower than might occur in other agreements. Whatever the royalty rate, the agreement creates early entry for the benefit of consumers. Moreover, viewed at the time of the agreement, the allegations of the complaint do not support the conclusion that this was a typical authorized generic agreement, *i.e.*, one where a manufacturer is wholly dependent on the brand company for its sales of the product. Rather, Teva already had a license to Abbott's TriCor patents and could enter the market with its own supply or the supply of a third party. The agreement merely gave Teva the *option* to purchase supply from another manufacturer. Ex. 3 (TriCor Term Sheet) at 5 ("Abbott hereby grants to Teva a time-limited *option* . . . on a non-exclusive basis . . . .") (emphasis added). Although it turned out that Teva was unable to obtain final approval for its product or to procure supply from another source, the FTC does not (and cannot) allege that at the time of the agreement, AbbVie knew this would be the situation.

Moreover, the complaint must allege what part of *this amount* is "unexplained" and not encompassed by the consideration specified in the TriCor supply option agreement—including the substantial payment of [redacted] Ex. 4 (TriCor Supply Option Agreement) §§ 1.90, 3.1, 5.1. Such an amount would not be "large" under any metric. But the key point here is that the FTC does not attempt to quantify what AbbVie would have thought this "payment" was worth to Teva, much less provide a "reliable foundation" that would permit this Court to determine whether any alleged "reverse payment" was "large." Absent such well-pleaded allegations, the complaint must be dismissed. *See Lipitor*, 2014 WL 4543502, at *20, *25 (dismissing allegations based on non-monetary settlements terms as "not plausible because they do not provide a reliable foundation or methodology to estimate the monetary value of [the brand company's] claim for infringement damages"); *see also Effexor*, 2014 WL 4988410, at *21–23; *Loestrin*, 2014 WL 4368924, at *11; *Twombly*, 550 U.S. at 556–57.

Nor can the FTC escape its burden under *Actavis* through conclusory allegations that "[t]he value of the compensation from Abbott to Teva in the TriCor authorized generic deal far exceeds either Teva's, Besin's, or AbbVie Defendants' actual or saved litigation costs from settlement of the AndroGel patent litigation," Compl. ¶ 122, or that "[t]he TriCor authorized generic deal was something Teva could not have obtained had it won the AndroGel patent infringement litigation," *id.* ¶ 124. Neither of these is the test for a "large" payment under *Actavis*. As to litigation costs, the Supreme Court stated that "avoided litigation costs" was but *one* of the "traditional settlement considerations" that do not raise antitrust concerns, along with "fair value for services" and "other[s]." *Actavis*, 133 S. Ct. at 2235–36. The Supreme Court thus expressly envisioned that a "payment" may exceed litigation costs but not raise any antitrust concerns under *Actavis* or otherwise. *See Effexor*, 2014 WL 4988410, at *22; *Lipitor*, 2014 WL 4543502, at *21–23. This

makes sense. Had the Supreme Court wanted to expressly define "large" as limited to litigation costs, it could have easily (and expressly) done so. The fact that it did not is telling. *See generally* Barry C. Harris et al., *Activating Actavis: A More Complete Story*, 28 Antitrust 83, 88 (Spring 2014).

Likewise, the Supreme Court in no way limited parties to settlement consideration that was within the "scope of the litigation," as the FTC now argues. Compl. ¶ 124. It is not unusual for a party to receive settlement consideration that it could not have obtained in the litigation. For example, a party that seeks only injunctive or declaratory relief in the litigation may receive a monetary payment as part of a settlement. A settlement in a patent case may also lawfully provide for a license on a different product or a global release as to additional patents (and pending patents) that cover the same product, or grant a supply or marketing agreement not related to the underlying litigation. These are common examples of the "traditional settlement considerations" that the Supreme Court envisioned in *Actavis*. 133 S. Ct. at 2236. The very example the Supreme Court provided in *Actavis* of a settlement that does not trigger antitrust scrutiny is something the litigants could not necessarily have obtained in the litigation—"compensation for other services that the generic has promised to perform[,] such as distributing the patented item or helping to develop a market for that item." *Id.* The FTC's novel scope-of-the-litigation theory has no basis in *Actavis* or any other law.

III. The FTC's Complaint Fails To Properly Allege That Any Delay To Teva's Non-Substitutable Product Would Result In Competitive Harm.

The FTC's complaint fails for the additional, independent reason that it does not contain well-pleaded allegations that Defendants' conduct caused any competitive harm. The crux of a claim under Section 5 of the FTC Act is that the complained-of conduct has a negative impact on competition. *See, e.g.*, *Actavis*, 133 S. Ct. at 2236 ("[T]he [reverse] payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence

constitutes the relevant anticompetitive harm."); *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 779–80 (1999) (similar); 15 U.S.C. § 45(n).

The FTC alleges that, but for the AndroGel settlement, Teva's AndroGel product would have entered the market prior to [redacted], and consumers would have saved money by purchasing this product rather than AbbVie's AndroGel product. *See* Compl. ¶¶ 141–51. But the facts the FTC alleges also reveal that this alleged harm is speculative and implausible, and thus insufficient to prove "significant anticompetitive effects." *Actavis*, 133 S. Ct. at 2237; *see also Twombly*, 550 U.S. at 555–56 & n.3; *In re Ins. Brokerage*, 618 F.3d at 319; *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 177 (3d Cir. 2010). This is so because Teva's product is *not* a generic substitute for AbbVie's AndroGel product. Compl. ¶¶ 33, 85. In the typical "reverse payment" case, the drug that the plaintiff alleges was kept from the market by the complained-of conduct is "AB-rated," meaning it is deemed "therapeutically equivalent" to the brand manufacturer's patented drug product and can automatically be substituted for the branded product in most states. *See Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1317 (D.C. Cir. 1998). As the FTC states in its complaint, a "unique competitive relationship exists between brand drugs and their generic equivalents," and "AB-rated generic drugs typically capture a significant share of sales [of the branded drug]" because both state laws and insurance policies "encourage the substitution of AB-rated generic drugs for their brand-name counterparts." Compl. ¶¶ 30–31, 140. The alleged competitive harm in the typical case is that, but for the complained-of conduct, an AB-rated product would have been available so that when a physician wrote a prescription for the branded product, in most cases the prescription would be filled with the lower-priced automatic substitute (the AB-rated generic).

But Teva's product is not AB-rated. Instead, the FDA assigned Teva's product a "BX" rating, meaning that Teva's product is deemed "therapeutically *inequivalent*" to AbbVie's AndroGel product. Compl. ¶ 85; Orange Book at xx. The impact of this BX rating cannot be overstated. Unlike with an AB-rated product, there are no laws or policies encouraging substitution of a product deemed therapeutically *inequivalent*. Indeed, in most states a pharmacist *cannot* legally substitute a drug unless it is deemed "therapeutically equivalent," either by the FDA in the Orange Book or by the pharmacist. *See* Jesse C. Vivian, *Generic Substitution Laws*, U.S. Pharmacist (June 19, 2008), *available at* http://www.uspharmacist.com/content/s/44/c/9787 (las visited on Nov. 10, 2014) (collecting state laws). Because of the BX rating, Teva's product is not a traditional "generic" alternative to AndroGel and will *not* automatically be substituted for AndroGel by pharmacists filling prescriptions for AndroGel. *See id.*; *see also Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 415 (D. Del. 2006).

The FTC's theory of harm here—that but for the AndroGel settlement consumers would have purchased Teva's alternative AndroGel product—thus depends on a series of implausible assumptions, *all* of which must be assumed for the FTC to state a claim. *First*, the FTC simply assumes that Teva would have brought its non-AB rated product to market, as well as that, in the but-for world, (1) Perrigo could have "achieved parity with Teva" in coming to market at the same time Teva did, Compl. ¶ 135, and (2) Perrigo's product would have received an AB rating and received that rating earlier than it actually did, *id.* ¶ 90. In other words, the FTC is asserting that Teva would have launched its non-substitutable BX-rated product, despite the purported fact that Perrigo would be launching an AB-rated, automatically substitutable product. As the FTC itself has noted, in the presence of an AB-rated generic, there simply is no market for a non-AB rated

product.[13] *See* FTC's Br. as Amicus Curiae at 9, *Mylan Pharms., Inc. v. Warner-Chilcott Pub. Ltd. Co.*, No. 12-3824 (E.D. Pa. Dec. 3, 2012), 2012 WL 7649225 ("As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product *disappears*." (emphasis added)). The FTC provides no well-pleaded facts explaining why this alleged course of action by Teva would be plausible.

Second, the FTC assumes that doctors would have learned about Teva's product. An AB-rated generic—which Teva's product was not—requires little, if any marketing, because the product will automatically be substituted when the physician prescribes the branded product. The generic manufacturer can thus "piggyback" off the substantial marketing efforts of the branded product. For a BX-rated product like Teva's, however, there is no automatic substitution. As a result, a physician must specifically prescribe the BX-rated product (not the branded product) in order for it to be dispensed. For this to happen, the physician must know the BX-rated product exists, which requires substantial marketing by the generic company. The FTC's complaint contains no allegations that physicians would have even *learned* of Teva's product, and it is speculative to assume that Teva would have invested substantial resources to market a product that was likely to gain few, if any, sales—especially in the face of AB-rated competition.

Third, even if Teva had launched the product and physicians had learned about it, the complaint contains no factual basis to infer that doctors would have actually *prescribed* Teva's product, instead of AbbVie's well-accepted AndroGel product or Perrigo's AB-rated generic alternative to AndroGel. AndroGel has been on the market since 2000, has been marketed heavily

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[13] The FTC's conclusory allegations about certain projections made by Defendant years ago does not change this analysis. *See* Compl. ¶¶ 34, 148–50. Importantly the FTC does not allege that any of those supposed projections was based on the circumstance postulated by the FTC, which includes the presence of an AB-rated alternative to a non-AB-rated product. Such models do not exist; rather, when there is an AB-rated product, there is no market for non-AB rated alternatives.

by AbbVie, and has obtained sales of hundreds of millions of dollars per year. Compl. ¶¶ 38, 41. It is not sufficient for the FTC to allege that Teva's product would have been less expensive, as it is well documented that physicians are not sensitive to price when prescribing treatments. *See generally* Judith K. Hellerstein, *The Importance of the Physician in the Generic Versus Trade-Name Prescription Decision*, 29 RAND J. of Econ. 108, 110–11 (1998) (discussing "evidence that physicians have little knowledge of actual drug prices" and that their prescription decisions are not price-sensitive). Moreover, even assuming hypothetically that either the doctor or the patient preferred a lower-cost generic alternative to AndroGel, *there is an alternative available*—from Perrigo—and there will be additional alternatives available from Watson and Par/Paddock in the future. Compl. ¶ 136; *see also In re AndroGel Antitrust Litig. (No. II)*, 888 F. Supp. 2d 1336, 1341 (N.D. Ga. 2012). Each of those other alternatives have been rated by the FDA to be "therapeutically equivalent" to AndroGel, while the FDA has explicitly declined to award that rating to Teva's product. It is simply implausible to assume that anyone would prescribe or purchase Teva's non-AB rated product when there are AB-rated alternatives on the market, including one that will be on the market at the same time as Teva's product. *See* Compl. ¶ 136.

Each of these assumptions is implausible on its own. Given that the FTC's case depends on *all* of these implausible assumptions being accepted, it simply cannot state an actionable claim. *See Twombly*, 550 U.S. at 555–56 & n.3; *In re Ins. Brokerage*, 618 F.3d at 319; *Great W. Mining & Mineral Co.*, 615 F.3d at 177.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss Count II of the FTC's complaint with prejudice, and dismiss Count I to the extent it is based upon an alleged "reverse payment" under *Actavis*.

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 12th day of November 2014 the foregoing Defendants' Motion to Dismiss (Public Version – Confidential Information Redacted) was filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. This document is available for reviewing and download. The undersigned certifies that he also served the foregoing Motion to Seal on all counsel of record via electronic mail.

/s/ Todd N. Hutchison
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